August 17, 2018

Cook Incorporated
Minjin Choi
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K181713
Trade/Device Name: Ultraxx™ Nephrostomy Balloon Catheter Set
Regulatory Class: Unclassified
Product Code: LJE, KOE, MAV
Dated: June 29, 2018
Received: June 28, 2018

Dear Minjin Choi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark R. Kreitz -S
2018.08.17 15:52:10 -04'00'

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181713

Device Name
Ultraxx™ Nephrostomy Balloon Catheter Set

Indications for Use *(Describe)*
The Ultraxx™ Nephrostomy Balloon Catheter is used to dilate the musculofascial tract, renal capsule, and parenchyma to establish and maintain a percutaneous tract.

The Inflation Device is recommended for use with balloon dilatation catheters to create and monitor the pressure in the balloon and to deflate the balloon.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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2.0 510(k) Summary

Ultraxx™ Nephrostomy Balloon Catheter Set

21 CFR §807.92

Date Prepared: June 29, 2018

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	Minjin Choi
Secondary Contact:	Andrew Breidenbach, Ph.D.
Applicant Address:	Cook Incorporated
	750 Daniels Way
	Bloomington, IN 47404
Contact Phone:	(812) 335-3575 x104901
Secondary Contact Phone:	(812) 335-3575 x105147
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	**Ultraxx™ Nephrostomy Balloon Catheter Set**
Common Name:	Catheter, Nephrostomy
Classification Regulation:	None, Product Code LJE
	21 CFR §870.1650, Product Code MAV
	21 CFR §876.5520, Product Code KOE
Device Class/Classification Panel:	Unclassified, Gastroenterology/Urology

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Predicate Devices:

- Ultraxx™ Nephrostomy Balloon Catheter (K171601) is the primary predicate device cleared for market by FDA on February 23, 2018.
- Cook Sphere Inflation Device (K032840) is the secondary predicate device cleared for market by FDA on March 3, 2004.

Device Description:

The Ultraxx™ Nephrostomy Balloon Catheter is a double-lumen catheter indicated for a nephrostomy procedure by dilating the musculofascial tract, renal capsule, and parenchyma to establish and maintain a percutaneous tract. The device is intended for limited duration use, not to exceed 24 hours in the body.

The Ultraxx Nephrostomy Balloon Catheter Set is comprised of the Ultraxx balloon catheter, Amplatz sheath, and inflation device. The Ultraxx Nephrostomy Balloon Catheter is constructed from a radiopaque nylon tubing with a dilatation balloon on its distal end. The outer diameter of the catheter is available in 6 French (Fr) with a working length of 55 centimeters (cm). The balloon of the catheter is constructed from polyethylene terephthalate (PET) and is available in nominal inflated diameters of 6 to 10 millimeters (mm) with a length of 15 cm. A radiopaque marker band is positioned on the distal end of the balloon catheter which confirms accurate placement of the catheter. The maximum rated balloon pressure is 20 atm. The Amplatz sheath is available in either polytetrafluoroethylene (PTFE) or a clear polyvinyl chloride (PVC). Both sheaths are available in inner diameters of 18, 24, or 32 Fr with a working length of 17 cm. The Cook Sphere Inflation Device was cleared on March 3, 2004 under K032840. The inflation device is a one-piece, plastic, disposable inflation device with a lock lever design to control the piston, a manometer, and a connecting tube with a male rotating adapter.

The set will be supplied sterile and is intended for one-time use. The set is packaged in a peel-open pouch with a three-year shelf life.

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Indications for Use:

The Ultraxx Nephrostomy Balloon is used to dilate the musculofascial tract, renal capsule, and parenchyma to establish and maintain a percutaneous tract.

The Inflation Device is recommended for use with balloon dilatation catheters to create and monitor the pressure in the balloon and to deflate the balloon.

Comparison to Predicate Devices:

The subject device and the predicate devices, Ultraxx Nephrostomy Balloon Catheter (K171601), and Cook Sphere Inflation Device (K032840), are substantially equivalent in that these devices have identical indications for use, design, dimensions, materials, method of operation, and fundamental technological characteristics. The modification from the predicate devices include:

- Packaging Configuration – The Cook Sphere Inflation Device (K032840) and the Ultraxx Nephrostomy Balloon (K171601) are provided together as a convenience kit.

Differences between the characteristics of the subject device and the predicate devices are supported by testing.

Non-clinical Studies:

As there have been no changes to the subject device with respect to the predicate devices (K171601 and K032840) that would affect biocompatibility, sterility, or performance, no additional biocompatibility, sterility, or performance testing was required. Packaging integrity testing following simulated distribution was performed.

Conclusion:

All predetermined acceptance criteria of the testing were met. Therefore, the results of these tests support a conclusion that the Ultraxx Nephrostomy Balloon Catheter Set will

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perform as intended and support a determination of substantial equivalence to the predicate devices.